State of California—Health and Human Services Agency

CLEAR FORM

Department of Health Services
Food and Drug Branch

BIENNIAL DRUG MANUFACTURING LICENSE RENEWAL APPLICATION

PLEASE COMPLETE THIS FORM FULLY—INCOMPLETE APPLICATIONS WILL BE RETURNED

See Page 2 for Instructions.

☐ NO CHANGES FROM PREVIOUS APPLICATION ☐ APPLICATION REFLECTS CHANGES OTHER THAN OWNERSHIP OR LOCATION

1. Name of Firm			9. Facility Operator (name and title)		
2. DBA (List additional DBAs on separate sheet if necessary.)			10. Facility Telephone Number ( )	11. Facility FAX Number ( )	
3. Facility Address (number, street)			12. 24-Hour Emergency Telephone Number ( )	13. E-Mail Address	
4. Facility Address (continued)			14. Correspondent (name and title)		
5. City	State	ZIP Code	15. Correspondent Telephone Number ( )	16. Correspondent FAX Number ( )	
6. Mailing Address (if different or P.O. Box number)			17. Country (if other than United States)	18. FDA CFN or FEI Number	
7. Mailing Address (continued)			19. Web site (URL)		
8. City	State	ZIP Code	20. Interstate Commerce ☐ Product Shipped ☐ Product or Raw Materials Received ☐ N/A		

21. Type of Ownership
☐ Individual/Sole Proprietorship ☐ Partnership ☐ Corporation/Limited Liability Company ☐ Nonprofit ☐ Other: _____

22. Corporate Name (if applicable)	State of Incorporation
23. Owners' or Officers' Names and Titles	Owners' or Officers' Names and Titles
24. Size of Facility (square feet):	Number of Employees at this Facility:

25. Stage of Manufacture at Date of Application (check all that apply)
☐ Manufacturing products ☐ Plant construction/design (Targeted Completion Date: _____)
☐ Validation – Completion Date: _____ ☐ Other (specify): _____

26. Intended Drug Destination (check all that apply)
☐ Commercial distribution ☐ Human clinical trials (investigational use) ☐ California distribution only ☐ U.S. distribution ☐ Export market

27. Type of Drug Product (check all that apply)
☐ Prescription* ☐ Over-the-counter ☐ Both* ***If *Prescription* or *Both* is checked refer to PDMA requirements on instruction page 2.**

28. Drug Products Manufactured at this Location (check all that apply)

☐ 700 Bulk pharmaceuticals (API)	☐ 704 Controlled substances (Schedule:_____DEA #: _____)	☐ 707 Biotech	☐ 711 Pre-IND
☐ 701 Medical gases		☐ 708 Biologics	☐ 712 Topical
☐ 702 Radioactive	☐ 705 Approved New Drug	☐ 709 Parenteral	☐ Other (specify):
☐ 703 Veterinary	☐ 706 Investigational New Drugs (IND)	☐ 710 Oral Dose (solid/liquid)	_____

29. Manufacturing processes/activities employed or planned in the manufacture of the drugs listed above. Indicate if these processes/activities will be done at this location (in-house) or by a contract. List other processes using additional sheets, if necessary. (Check at least one or more.)

Processes/Activities	In-house	Contract	Processes/Activities	In-house	Contract
Aerosolization	☐	☐	Powder Mixing	☐	☐
Aseptic	☐	☐	Relabel Only	☐	☐
Coating	☐	☐	Repackage Only	☐	☐
Emulsification	☐	☐	Sterilization	☐	☐
Encapsulation	☐	☐	Suspension	☐	☐
Fermentation/tissue culture viral vector/gene therapy	☐	☐	Tableting	☐	☐
			Other (Specify):_____	☐	☐
Liquid Mixing	☐	☐			

30. Payment Codes (Check only one code—see page 2 for schedule)
☐ **A—$2600** ☐ **B—$1700**

MAKE CHECKS PAYABLE TO: DEPARTMENT OF HEALTH SERVICES
See page 2 for mailing address

31. **License Fees Due:**	**Enter Each Fee Below:**
a. License Fee (see #30)	**$**
b. **PDMA*** ($200 If Applicable – see page 2)	**$**
c. Late Fee ($10 if over 30 days late)	**$**
d. **Total Payment Due**	**$**

The Food and Drug Branch MUST BE NOTIFIED of any change in the application information as provided by CA Health and Safety Code, §111630.

By signature, I declare under penalty of perjury that all information provided herein is true and correct.

32. Signature	Printed Name	Title	Date

PLEASE DO NOT WRITE BELOW THIS LINE.

License Number	Expiration Date	Date Received	Payment Type	Amount
				$

BIENNIAL DRUG MANUFACTURING LICENSE RENEWALAPPLICATION INSTRUCTIONS

A separate application is required for each place of business. Please complete and/or amend this application as is most appropriate to your facility. Include the appropriate fee for each application and make check payable to: DEPARTMENT OF HEALTH SERVICES. The fee must accompany this application or it cannot be processed. **Please apply within 30 days of expiration**; failing to do so requires an additional $10 penalty added to the renewal fee before the license is issued. Unsigned or incomplete applications cannot be processed. The following are further instructions on how to complete this application:

Renewal Status: Place an (X) in the box next to "No Changes from Previous Application" if your firm does not have any changes to report since you last applied for or renewed a Drug Manufacturing License at this location under the current ownership. Place an (X) in the box next to "Application Reflects Changes…", if your firm has new information to report other than a location or ownership change, and you are renewing that license. **This license is non-transferable.** If your firm has changed location, ownership, or both, use the application titled "New Drug Manufacturing License Application" (EH 52N). For any section that does not apply to your company, please indicate with (N/A). Do not leave any sections blank.

1. **Name of Firm:** Enter full name of business, corporation, company, or organization applying for licensure.
2. **DBA:** Enter any other name(s) your company is doing business as.

3.–5. **Facility Address:** Enter the number, street, city, state, and ZIP code for this facility location.

6.–8. **Mailing Address:** Enter the full mailing address if different from the facility address.

9. **Facility Operator:** Enter the full name(s) of the person(s) in charge of drug manufacturing at this facility and their title(s).
10. **Facility Telephone Number:** Enter daytime business telephone number of this facility.
11. **Facility FAX Number:** Enter facility FAX number.
12. **24 Hour Emergency Telephone Number:** Enter telephone number to be called in the event of an emergency.
13. **E-mail Address:** Enter facility e-mail address.
14. **Correspondent:** Enter the name of the person to contact for information regarding this application and their title.
15. **Correspondent Telephone Number:** Enter the daytime business telephone number of the contact person.
16. **Correspondent FAX Number:** Enter the daytime business FAX number of the contact person.
17. **Country:** Enter the country where your facility is located, if outside of the United States.
18. **FDA CFN or FEI:** Enter your US Food and Drug Administration Central File Number or Federal Establishment ID, if known.
19. **Web site:** Enter the Web site address for your business, if applicable.
20. **Interstate Commerce:** Place an (X) in all appropriate boxes that correctly describe your business' receipt or distribution of products or materials through or into interstate commerce.
21. **Type of Ownership:** Place an (X) in the box next to the appropriate legal description of the facility's ownership.
22. **Corporate Name:** Enter corporate name if applicable. Enter state of incorporation if applicable.
23. **Owners' or Officers' Names:** List the business owners' or officers' names and titles. *USE ADDITIONAL SHEETS IF NECESSARY*.
24. **Size of Facility**: Indicate the most appropriate size (in square feet) at this facility and the approximate number of employees at the facility.
25. **Stage of Manufacture:** Place an (X) in the box next to the stage of manufacture your products are in at the time of application submission. Check all that apply.
26. **Intended Drug Destination:** Place an (X) in the box adjacent to the destination(s) for your manufactured products. Check all that apply.
27. **Types of Products:** Place an (X) in each box that applies to the type of drugs manufactured or to be manufactured. For human prescription (Rx) drug manufacturers, refer to PDMA requirements below*****.
28. **Products Manufactured:** Place an (X) in the box adjacent to each product area box that applies to the drugs manufactured or to be manufactured. Use additional sheets if necessary.
29. **Manufacturing Processes:** Place an (X) in the columns adjacent to all applicable processes to be performed in-house and/or contracted-out. Leave line blank if the indicated process will not be applied to the manufacturing of listed drugs. List additional processes or methods as needed herein or on additional sheets if necessary.
30. **Payment Fee Code:** Your renewal license fee is based on the application type, number of employees, amount of sales, and the type of drugs being manufactured at the facility.

Application Type	*Biennial Fee*	*Late Fee*	*Payment Interval*	*Payment Code*
Renewal	$2600	$10	Biennially on Renewal	A
Renewal (*****Special/Small Firms***)	$1700	$10	Biennially on Renewal	B

***** Special or Small Firms are types limited to companies that 1) repack medical gas only, OR 2) employ three or fewer people and have an annual sales of less than $500,000.***

*** PDMA (Prescription Drug Marketing Act) Requirements:** *If your firm manufactures human prescription (Rx) drugs, an additional **$200.00** must be added to the license renewal fee and a Disclosure Statement (Form EH 53) must be submitted for each person listed on lines #9 and #23 (instructions provided therein). Information relevant to the PDMA, (e.g., Disclosure Statements and Applicant Fingerprint Live Scan requirements) can be reviewed at:* http://www.dhs.ca.gov/fdb/HTML/Drug/PDMA.htm.

31. **License Renewal Fee Due:** Enter appropriate fees due.
    a. Enter license fee according to payment codes in #30.
    b. Add $200 PDMA fee if it applies to your firm. See PDMA requirements above*****.
    c. A $10 late fee due, if renewal application is over 30 days late.
    d. Enter Total Payment Due by adding a, b and c.
32. Sign the application, print your name, print your title, and enter the date. All signatures must be original.
    Make checks payable to: DEPARTMENT OF HEALTH SERVICES Mail Application and Check to: (below)

Regular Mail: California Department of Health Services
Food and Drug Branch - Cashier
MS 7602
P.O. Box 997435
Sacramento, CA 95899-7435

Overnight Mail: California Department of Health Services
Food and Drug Branch - Cashier
1500 Capitol Avenue, MS-7602
Sacramento, CA 95814

If further questions exist, please contact the FDB License Desk for Drug Manufacturing at (916) 650-6500, or visit our web site at: http://www.dhs.ca.gov/fdb/.